MAY - 3 2000

K000348

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS:
COLORADO MICRODISSECTION NEEDLE

General Information

Proprietary Name:	Colorado MicroDissection Needle
Common Name:	Electrode, Electrosurgical
Classification Name(s):	Electrode, Electrosurgical
Classification Code(s):	JOS 878.4400
Submitter:	Stryker Leibinger 4100 East Milham Avenue Kalamazoo, MI 49001 800-253-7370
Submitter's Registration #:	1811755
Manufacturer's Registration #:	1811755
Contact Person:	Nicole L. Petty Regulatory Analyst 800-253-3210 x3388
Summary Preparation Date:	April 24, 2000

Device Description

The Colorado MicroDissection Needle is a monopolar electrosurgical instrument consisting of a tungsten tip, stainless steel housing and several layers of insulation. The product is sterile, single-use device for precise tissue cutting, dissecting and cauterizing. It is most commonly used in surgical procedures for which minimal tissue necrosis, bleeding and surgical field smoke is desired. The needle is compatible with all standard electrosurgery generators. Both uninsulated and insulated needles are offered. Insulated needles have a 3 mm exposed tip.

Intended Use

The Colorado MicroDissection Needle is a monoplar electrosurgical instrument used for precision soft tissue dissection. It is a single-sue device intended for cutting, dissecting and cauterizing soft tissue. The Colorado MicroDissection Needle is not intended for use in the central nervous system or in the central circulatory system.

Substantial Equivalence

The Stryker Colorado MicroDissection Needle is equivalent of the previous version of the product manufactured by Colorado Biomedical, Inc. and cleared with K881763.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2000

Ms. Nicole L. Petty
Regulatory Affairs Analyst
Stryker Leibinger
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K000348
Trade Name: Colorado MicroDissection Needle
Regulatory Class: II
Product Code: GEI
Dated: February 1, 2000
Received: February 3, 2000

Dear Ms. Petty:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K000348

510(k) Number (if known): not known

Device Name: Colorado MicroDissection Needle

Indications For Use:

The Colorado MicroDissection Needle is a monopolar electrosurgical instrument used for precision soft tissue dissection. It is a single-use device intended for cutting, dissecting and cauterizing soft tissue. The Colorado MicroDissection Needle is not intended for use in the central nervous system or in the central circulatory system.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lachman

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000348

Prescription Use ✓ OR Over-The- Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)